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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,797	07/23/2001	Jacques Diaz	3806.0510-00	2702

7590 05/17/2004  
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Washington, DC 20005-3315

EXAMINER

KRISHNAN, GANAPATHY

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/909,797	DIAZ ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ganapathy Krishnan	1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-16,18-46 and 56-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10-16, 18-37 and 59-70 is/are allowed.
- 6) ☒ Claim(s) 1,2,5-9,38-46 and 56-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

The amendment filed January 14, 2004 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 3, 4, 17 and 47-55 have been canceled.
2. New Claims 56-70 have been added.
3. Claims 1, 2, 5-8, 10-16, 18, 20-23, 26-35 and 39-46 have been amended.
4. Remarks drawn to rejections under 35 USC 112 and 102.

Claims 1, 2, 5-16, 18-46 and 56-70 are pending in the case.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112***

The rejection of claims 10-16 and 18-37 under 35 USC 112, first paragraph has been overcome in view of the applicants' arguments.

The rejection of claims 39, 40, 42, 43, 45 and 46 under 35 USC 112, second paragraph has been overcome by amendments to the claims.

#### ***Claim Rejections - 35 USC § 102***

Claims 1-2, 5-9 are rejected under 35 USC 102(e) as being anticipated by Mardiguian (US 6384201) is maintained for reasons of record.

Applicant's argue that even though Mardiguian discloses compositions having an average molecular weight in the range of 2000-4000 daltons, Mardiguian does not

Art Unit: 1623

disclose compositions of 3000 daltons or less having an antiX<sub>a</sub> activity in the range of 110-150 IU/mg.

Applicant's arguments are not found to be persuasive. Mardiguian discloses compositions of heparin having molecular weight lying between 2000-4000 daltons and the antiX<sub>a</sub> and anti II<sub>a</sub> activity in the range as instantly claimed (col. 2, lines 22-26, col. 5, lines 20-43 and col. 6, lines 27-30). The molecular weight range of the heparin of Mardiguian encompasses the molecular weight range as instantly claimed. The antiX<sub>a</sub> and anti II<sub>a</sub> activity and the ration of the two is also in the range as instantly claimed (col. 5, lines 20-23). The heparin composition has 10 to 12 saccharide units and one end has a 4, 5-unsaturated glucuronic acid 2-O-sulfate unit and the composition is also shown to contain sodium (alkali metal) salt. These teachings anticipate instant claims 1-2 and 5-9.

Claims 38, 41 and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Mardiguian (US 6384021) is being maintained for reasons of record.

Claim 38 is drawn to a method of treating venous thrombosis using the composition of claim 1 and claims 41 and 44 are drawn to a method of treatment of arterial thrombosis using composition of claim 2. Mardiguian discloses that his compositions are useful for the treatment of venous and arterial thrombosis. Since Mardiguian's composition encompasses the composition of instant claims 1 and 2 the method of instant claims 41 and 44 are anticipated.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1623

A person shall be entitled to a patent unless –

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 56-58 are rejected under 35 U.S.C. 102(e) as being anticipated by Mardiguian (US 6384021).

Mardiguian discloses a composition of heparin in the molecular weight range as instantly claimed that has an anti Xa activity between 100 and 150 IU/mg and an anti IIa activity of less than or equal to 10 IU/mg. (see col. 5, 20-44). The heparin composition has 10 to 12 saccharide units and the one end unit has a 4,5-unsaturated glucuronic acid 2-O-sulphate unit (col. 2, 22-26 and col. 5, see general formula). The products have an antiXa:antiIIa activity ratio of greater than 10:1. The composition is also shown to contain sodium (alkali metal) salt. This disclosure of Mardiguian meets the limitations of claims 56-58. The method of obtaining the composition comprising the metal salt of the sulfated polysaccharide as recited in claim 56 is not given patentable weight. Claim 56 is a product by process claim. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps.

“Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process

Art Unit: 1623

claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claims 39, 40, 42, 43, 45 and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Mardiguian (US 6384021).

Mardiguian discloses a composition of heparin in the molecular weight range as instantly claimed that has an anti Xa activity between 100 and 150 IU/mg and an anti IIa activity of less than or equal to 10 IU/mg. (see col. 5, 20-44). The heparin composition has 10 to 12 saccharide units and the one end unit has a 4,5-unsaturated glucuronic acid 2-O-sulphate unit (col. 2, 22-26 and col. 5, see general formula). The products have an antiXa:antiIIa activity ratio of greater than 10:1. The composition is also shown to contain sodium (alkali metal) salt. Mardiguian also discloses that the compositions of his invention are useful in the prophylaxis and treatment of venous and arterial thrombosis (col. 2, lines 28-31 and col. 6, lines 35-44). This disclosure of Mardiguian is seen to meet the limitations of the method claims 39, 40, 42, 43, 45 and 46.

### ***Conclusion***

1. Claims 1-2, 5-9, 38-46 and 56-58 are rejected.
2. Claims 10-16, 18-37 and 59-70 which are drawn to a method of preparing at least one alkali or alkaline earth metal salt of at least one sulfated polysaccharide of heparin wherein the non obvious phosphazene, imidazolate and 1,5,7 triazabicyclo-[4.4.0.]-dec-5-ene are used as a base in the depolymerization step are neither taught are fairly suggested by the prior art of record.

Art Unit: 1623

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

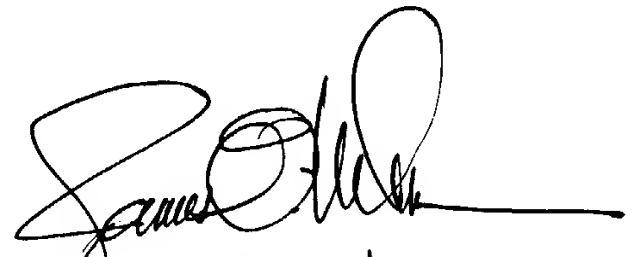
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK



James O. Wilson  
Supervisory Patent Examiner  
Art Unit 1623